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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,781	02/09/2004	Kim Gene Friesen	2664H-000020/US	8857

7590 01/24/2007
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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/774,781	Applicant(s) FRIESEN ET AL.	
	Examiner Shirley V. Gembeh	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed **11/4/06** presents remarks and arguments to the office action mailed **5/4/06**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

Applicant statement with regards to the International Search Report for PCT/US2005/00424 and written opinion PCT/US2005/00424 that the references therein are given in the IDS.

In response, submission of a written report is not a publication, since accordingly these where included for completeness, does not mean that they should be considered as a literature or a publication.

Status of claims

Claims 1-17 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-6, 8-11 and 13-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Applicant has not provided a description of the structure of a representative number of compounds nor a description of the chemical and/or physical characteristics of a representative number of compounds nor a description of how to obtain a representative number of specific compounds.

In other words, the Applicant has not described with sufficient clarity what these sulfur containing amino acid contemplated. In order to overcome this rejection, Examiner suggests including the limitations of claim 2.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 10-11 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Florio US 5,840,715.

Applicant traverses (see page 12-14) of remarks, that Florio does not use or disclose a sulfur containing amino acids for treatment of arthritis.

In response, contrary to Applicants' traversal, the reference teaches S-adenosyl-methionine (see col. 3, line 40) as in claim 3 is administered and found that it was more effective than motrin (see col. 3, lines 41-50) and manganese (see abstract). Further, Applicant administered a glycosaminoglycan polysulfate which is a sulfur containing amino acid and contains at least one sulfur. Please note that the claim 1 is broad and does not call for any particular sulfur containing amino acid and manganese. Next, the compound is used for the treatment of osteoarthritis.

Applicant's arguments filed have been fully considered but they are not persuasive. The reasons given above and the rejection is maintained as in the last office action of record.

II. Claims 1-2, 10-11 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by www.dhea.com/jointrec.htm (1998)

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Applicant traverses, that the reference does not teach “a sulfur containing amino acid”, emphasis on the said verbatim and that the the site is a commercial website that sells many different supplements:

In response, the claim calls for a sulfur containing amino acid that is used for rebuilding cartilage, whether it is a commercial product or not, it has been used before, for the treatment of arthritis and has the claimed limitations therein.

Applicant's arguments filed have been fully considered but they are not persuasive. The reasons given above and the rejection is maintained as in the last office action of record.

III. Claims 1-2, 10-11 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Henderson et al US 6,255,293.

The same reasons are applied here as given supra.

Applicant's arguments filed have been fully considered but they are not persuasive. The reasons given above and the rejection is maintained as in the last office action of record.

Maintained Claim Rejections - 35 USC § 103

Claim 1- 5 and 10-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Florio US 5,840,715 taken with Henderson et al US 6,255,293 and www.dhea.com/jointrec.htm in view of Myers US 6,911,215 B2.

Applicant's arguments filed have been fully considered but they are not persuasive. The reasons given above for the 102 rejections are applied here and the

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rejection is maintained as in the last office action of record. The motivation to combine or to use a sulfur containing compound comes from the administration to treat a osteoarthritis and all the cited references have used the claimed compounds and in combination to treat a type of cartilage disorder. Both references teach treating the same type of disease disorder, thus one of ordinary skill is motivated to combine the teachings for the treatment of the same type of disease. The claimed subject matter is not patentably distinct over the prior art.

II. Claim 6-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Florio US 5,840,715 taken with Henderson et al US 6,255,295 and www.dhea.com/jointrec.htm in view of Myers US 6,911,215 B2 as applied to claims 1-5 and 10-17.

Applicant's arguments filed have been fully considered but they are not persuasive. The reasons given above for the 102 rejections are applied here and the rejection is maintained as in the last office action of record. The motivation to combine or to use a sulfur containing compound comes from the administration to treat osteoarthritis and all the cited references have used the claimed compounds or Harper et al in combination to treat a type of cartilage disorder. The claimed subject matter is not patentably distinct over the prior art.

Double Patenting

Applicant's request that the Double Patenting rejection be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until withdrawn.

Claims 1-17 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 - 20 of U.S. Patent Application No. 11199350. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

Claims 1-17 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 - 33 of U.S. Patent Application No. 10774951. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
1/11/07

Ardin H. Marschel 1/11/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER